

cause adverse health effects in humans. Different types of toxicology studies can be conducted to evaluate potential toxic responses. Lifetime bioassays in rodents are recommended by the FDA as the most reliable means of determining the carcinogenic potential of exposure to a given agent. For most drugs and foods, the FDA requires lifetime bioassays in both rats and mice. Short-term studies (i.e., *in vitro* and short-term *in vivo* assays) can be used to detect potential genotoxic effects. Such studies can also provide information for evaluating possible mechanisms of action through which adverse effects can occur. When conducting genotoxicity test batteries, *in vitro* tests are generally considered to have less predictive value than tests in whole animals.

Similar requirements and guidelines exist for the U.S. Environmental Protection Agency (EPA) and various international regulatory agencies. They differ slightly in specific requirements, but all basically consider the weight of evidence from the test article's similarity to known carcinogens, the evidence from genotoxicity and other studies, and the outcome, in terms of increased tumor incidence by tissue, in the lifetime animal bioassays.



The toxicology portion of the research program will encompass studies in whole animals and cell cultures

For all guidelines, there is the intention that exposure to the test article should simulate, as closely as possible, actual conditions of human exposure. The maximal limits of the dosages are determined by experimental conditions and physiological considerations.

The research program, by following accepted approaches to determine carcinogenic potential, should provide results acceptable to regulatory review. The quality database derived from these studies will allow informed scientific decision-making based upon what we know, and permit us to dispel fear and apprehension arising from what we do not know.



Epidemiology studies require a great deal of computer power to do data linkage

HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN TOXICOLOGY RESEARCH

Literature Review

Phase One began with a completion of a comprehensive literature review that served as the basis for the SAG's *Research Agenda*. This established the framework and terms of reference around which the toxicology research program would be developed, including the methodology for reviewing toxicology research proposals.

Participation in Development of *In Vivo* and *In Vitro* Exposure Systems

Members of the Toxicology Committee assisted in the development of an exposure system by offering advice on the biological feasibility of a head-only exposure system for animal studies.

Proposals

In August 1994, the SAG published a request for proposals (RFP) in *Science* magazine, the BEMS Newsletter, and the SAG newsletter, *Cellular Telephone Update* (now *Wireless Technology Update*). Specific proposals were requested for *in vivo* and *in vitro* studies examining the possible genetic effects of typical

exposures from portable cellular telephones. The RFP resulted in responses from investigators in a variety of scientific disciplines relating to genotoxicity. In addition, a number of investigator-initiated proposals (i.e., not in response to the published genotoxicity RFP) were also received. A consistent and thorough evaluative procedure was developed to carefully assess the potential relevance of any submitted proposals to the SAG research plan. Particular consideration was given to those proposals that fell under the Tier I — product safety — category.

Following the review of a number of proposals, it became apparent that there was a need to establish appropriate dosimetry guidelines and characterize both *in vivo* and *in vitro* exposure systems. The WTR will pursue relevant proposals of biological research once the exposure systems are developed.

DNA Action Plan

A DNA Action Plan was created to provide a framework for the investigation of potential radiofrequency radiation-induced genotoxicity. As part of the plan, the SAG convened an expert panel on the Single Cell Gel (SCG) assay in October 1994. In light of new data, the SAG recognized the need for specialized advice concerning the relevance of the SCG assay and the interpretation of current literature. The SCG Expert Panel prepared a position paper to advise the SAG on the assay and its strengths, limitations, and usefulness as a test for genotoxicity and its relationship to other endpoints. Also, several data sets were discussed, with particular emphasis on results from a study that used brain cells from radiofrequency radiation-exposed rats. The panel recommended that the study using microwave (2450 MHz) radiation be repeated as published by the original investigators and also repeated with correction of the deficiencies noted by the panel by either the original or alternate investigators. Questions concerning the assay and when it should be repeated were formally presented to the Peer Review Board in late 1994. The WTR has decided to repeat the study based on the board's recommendation, and is currently issuing an RFP for the work.

Tumor Promotion Expert Panel

The organization of the Tumor Promotion Expert Panel was completed during Phase One and the panel convened in the first week of 1995. Panel members are expected to assist the WTR in evaluating *in vivo* and *in vitro* promotion studies involving radiofrequency radiation, the relevance of animal promotion models to humans, and possible mechanisms of tumor promotion by radiofrequency radiation. The panel will review what is currently known from the literature regarding the study of radiofrequency radiation on tumor promotion as well as consider work in progress that has significant bearing on this question. The panel will publish a concept paper in 1995.

DNA/Genotoxicity Expert Panel

The framework for the DNA/Genotoxicity Expert Panel was established during Phase One. The panel will include experts in the fields of DNA damage and repair, molecular biology, and *in vivo* and *in vitro* genetic toxicology. Panel members will assist the WTR in evaluating and making recommendations on mechanistic as well as genotoxicity studies which have been designed to assess the potential effects of radiofrequency radiation on DNA. They will also review the available literature and provide assistance in evaluating incoming proposals.

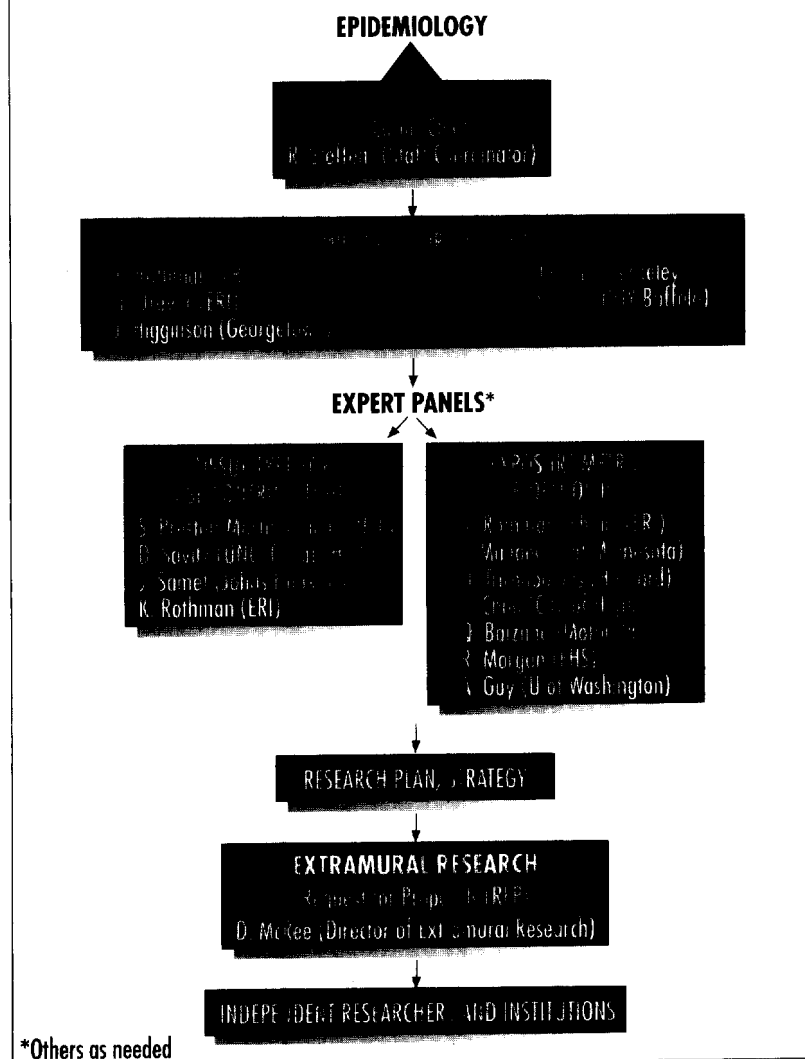
▲ DEFINITION OF EPIDEMIOLOGY

Epidemiology research encompasses epidemiological evaluations and longitudinal surveillance of wireless technology including cellular telephone users and employing appropriate measures of real-life exposures. A series of epidemiology studies of varying but appropriate study designs has been planned to assess the possibility of cancer as a biological outcome of exposure to wireless communication instrument usage. Different study designs (cohort, case-control, cross-sectional, etc.) are necessary to fully evaluate possible causal associations. Replication of findings and consistency in the epidemiological database is served by commencing various studies simultaneously.

"The cellular telephone industry is sponsoring a research initiative through a science advisory board that includes both [epidemiological and laboratory research] that federal officials say is needed."

General Accounting
Office (GAO)
Report on Safety of
Cellular Telephones
November 1994

RISK EVALUATION RESEARCH: Structure of Epidemiology Research Component and Decisionmaking Process



HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN EPIDEMIOLOGY RESEARCH

Pilot Studies of Cellular Telephone User Records

Dr. Ken Rothman at Epidemiology Resources, Inc. (ERI), is currently conducting pilot studies of user record utility examining the appropriate applications of cellular telephone user records, information on location of cellular system sites, and other factors. These studies will provide greater understanding of the

types of information that are available and useful in order to design appropriate epidemiology studies and interpret the results. A paper describing the results of a survey conducted using a sample of this user cohort (N=5,550) to validate the correlation between user records and self-reported phone use is nearing completion and will undergo the formal peer review process for submission to the scientific literature.

Mortality Study

ERI will also compare the mortality by cause-of-death among users of portable cellular telephones with the corresponding age- and gender-specific rates among mobile telephone users. This study will follow a protocol reviewed by the Peer Review Board. These comparisons will be summarized using Standardized Mortality Ratios (SMR). ERI will also examine the SMR of categories of telephone users, using various indices of exposure. The analyses will be done separately for each phone company, as well as a combined analysis of data from all phone companies. Additional cellular telephone companies will be recruited to participate in the cohort study in order to reach an overall sample size of approximately seven million cellular phone users.

Validation Studies

Validation studies currently in progress will assess the accuracy of phone record data in determining the primary user of the cellular phone. To assure the highest quality data and scientific interpretation, all studies will be subjected to ongoing scientific peer review by the WTR and the Peer Review Board.

Concept Papers

A concept paper describing exposure assessment issues regarding cellular telephone usage is in the final development process. The paper is being written by an expert panel chaired by Dr. Ken Rothman at ERI and including Drs. George Carlo, Arthur Guy, Jack Mandel, Quirino Balzano, C. K. Chou, Robert Morgan, and Dimitrios Trichopoulos. Consideration has been given to such issues as the difference from the perspective of dosimetry between ten one-minute phone calls and one ten-minute phone call. The paper also explores the appropriate ways of handling cellular telephone user records, and information on location of cellular system sites. The paper will offer a greater understanding of the kinds of information that are available and useful in order to design appropriate epidemiology studies and to interpret the results. This paper is nearing completion and will undergo the formal peer review process leading to publication.

A concept paper addressing meaningful outcomes for epidemiology studies of cellular telephone users will focus on such issues as the types of tissues likely to be affected by cellular telephone use considering current dosimetric modeling results. A panel of experts in the etiology of brain cancer and other relevant types of cancer was convened in January 1995 leading to a paper that will be incorporated into

the exposure assessment paper (above). The panel is chaired by Dr. Susan Preston-Martin, and includes Drs. Rothman, Carlo, Guy, David Savitz, and Jon Samet.

Papers will be developed by outside investigators addressing important exposure issues relevant to wireless communication instruments users to provide guidance in the epidemiology studies. The WTR will consider issues such as the importance of handedness in determining exposure, the importance of potential confounders such as wire-rimmed eye glasses, and the role of variables such as location of telephone call with respect to proximity to a base station. The unique exposure characteristics of cellular telephones must be incorporated into the evaluation of potential human effects, such as intermittent versus continuous use, and the individual characteristics of different phone models. The papers will be used to evaluate the adequacy of the assessment of human exposure to radiofrequency radiation in order to lay the foundation for the proper design and interpretation of subsequent epidemiology studies.

Exposure Weighting Scheme

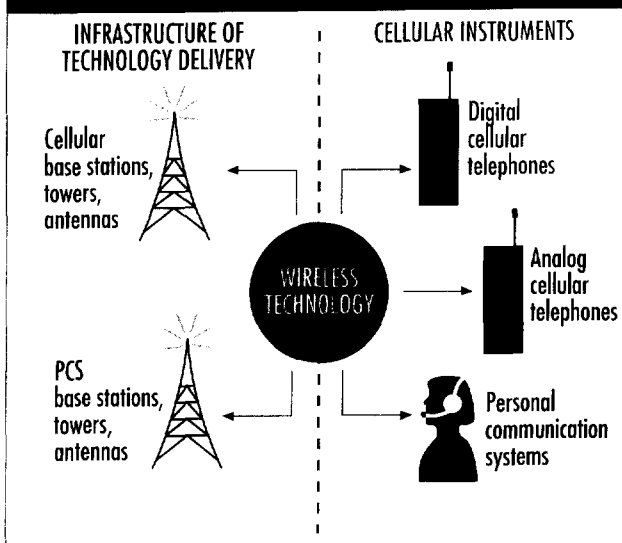
Using data provided by McCaw Cellular Communications, Inc., an exposure weighting scheme will be developed to measure the density of cell sites across the United States and proximity of cellular telephone users to a base sta-

tion, as an estimate of power density. This information will be used in the epidemiology exposure metric.

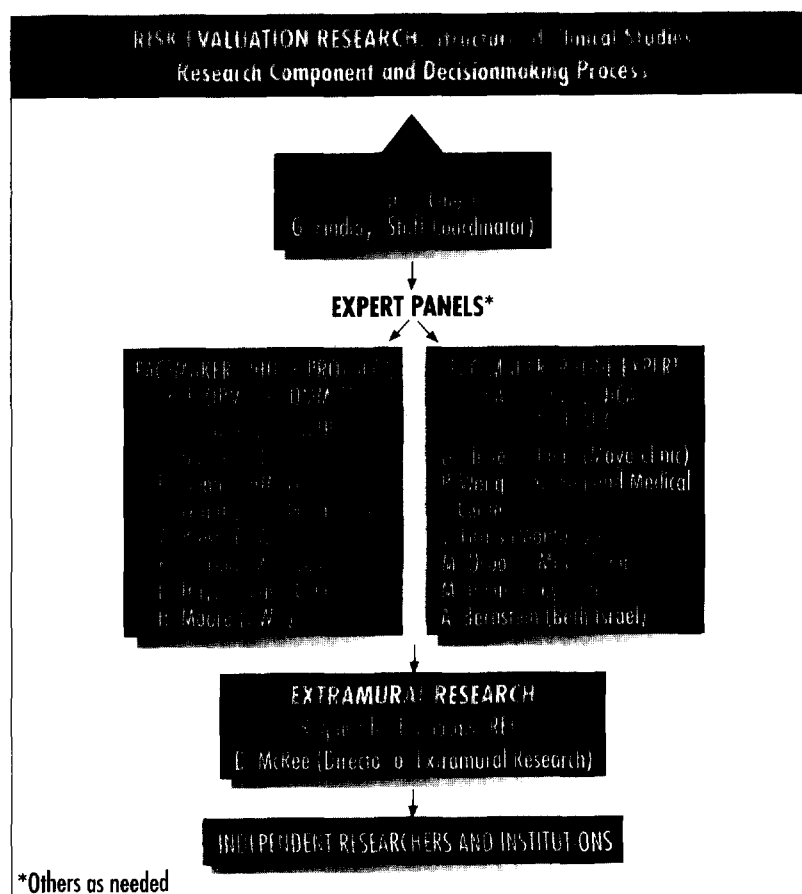
▲ DEFINITION OF CLINICAL STUDIES

The clinical discipline was introduced into the Risk Evaluation Research program in 1994 when a potential public health problem involving interference from cellular phones with implanted pacemakers was identified through the Ongoing Surveillance program. Upon evaluating the issue's relevance to the *Research Agenda*, the SAG determined that a clinical study of pacemaker patients was necessary. The SAG established Clinical Studies as a distinct component of the Risk Evaluation Research program to address the interference issue, and also to have a mechanism in place to handle other clinical studies, if the need arises.

EXPANSION OF RESEARCH AGENDA



The subject matter that the SAG initially sought to study — health effects from portable cellular telephones — has now evolved into the evaluation of all wireless communication technology, including cellular base station facilities, personal communication instruments, and electromagnetic interference.



Clinical studies are planned experiments that involve human patients and are designed to observe some form of exposure. The outcomes of an exposure group are generally compared to the outcomes of a group of patients receiving a control exposure. Patients in both the groups are enrolled and followed over the same time period. In clinical studies, one uses results based on a limited sample of patients to make inferences about a general population.

HIGHLIGHTS, DECISIONS, AND PROJECTIONS IN CLINICAL STUDIES

Protocol Development

The primary activity within the clinical studies component of the Risk Evaluation Research program was the organization and development of a protocol for the clinical study of pacemakers and cellular phones. The SAG took the lead in organizing a protocol development committee that involved a cooperative effort among the FDA; the Center for the Study of Wireless Electromagnetic Compatibility at the University of Oklahoma; physicians from the Mayo Clinic, Mt. Sinai Medical Center, and the George Washington University

Medical Center; the SAG; and representatives of the pacemaker and cellular telephone industries. Dr. George Carlo served as chairman of the committee. The committee convened for several meetings and conference calls and was responsible for providing comments on each draft of the protocol. Representatives of the SAG also met with various expert working groups to discuss technical issues regarding the protocol.

Entitled *A Clinical Study to Assess the Potential for Hand-Held Wireless Telephones to Interfere with Implanted Pacemakers*, the study will be funded by the WTR and conducted at multiple institutions. All patients that present will be eligible, providing a representative sample of pacemakers, and four wireless technologies currently or soon to be available in the United States will be tested. The protocol has been finalized and results should be available by the end of 1995.

The clinical study will provide information on the interaction between cellular telephones and implanted pacemakers. To assess the public health impact of any potential interference, an expert panel of cardiologists has been formed to discuss and define the clinical significance of electromagnetic interference. The report from this group will serve as rationale for interpretation of the clinical study.

PROFILE OF RISK MANAGEMENT RESEARCH

The wireless technology research program has been designed to facilitate simultaneous work on the evaluation of potential health risks and on the development of strategies and tools to mitigate or to manage any identified health risks. The goal of the program is to bring decisionmakers to a state of readiness to manage risk as the risk evaluation research is completed.

Risk management research under the wireless technology research program is being coordinated through six distinct working groups covering the following areas:

- Wireless instrument design
- Product label modifications
- Product certification
- Usage restrictions
- Wireless technology infrastructure modifications
- Education and scientific outreach

Each of these six areas is coordinated by a working group charged with the development of intervention options and strategies specific to their area of focus. Working group members include scientists and engineers from the WTR, academia, and industry. A report enti-

tled *Potential Public Health Risks from Wireless Technology: The Development of Data for Science-Based Risk Management Decisionmaking, Interim Status Report* was developed with input from the risk management committees.

The SAG originally forwarded the status report to the FDA to update it on the SAG's progress in the area of risk management in the summer of 1994. An updated copy was sent to the President of the Cellular Telecommunications Industry Association (CTIA) in November 1994.

Product Design Changes

The Product Design Changes Working Group developed a process to evaluate potential design change options and considered options for a peer review and evaluation process that is timely and fair, without giving undue marketplace advantage to one company over another. The group considered a number of design change possibilities, including a network-implemented call duration tone that would allow the user to know when the call reaches a certain length; a portable-implemented call duration indicator that would allow the user to access call duration information at their discretion; various vehicular antenna and regular antenna options; antenna shields, including review of existing shields currently in the marketplace; voice-operated transmission where voice activation dictates when the

RISK MANAGEMENT RESEARCH: Working Groups Responsible for Development of Strategy for Necessary Implementation and Intervention

WORKING GROUP CHAIRS

LABELING

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Motorola

CERTIFICATION

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DESIGN CHANGE

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INFRASTRUCTURE (BASE STATIONS)

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PUBLIC EDUCATION

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Volpe Communications

USAGE RESTRICTIONS

G. Carlo
WTR/SAG Chair

radiofrequency signal is sent or received; and audio headsets.

Evaluation criteria developed by the working group for these options include whether the design is available for all customers, whether the instrument will retain quality of operation, whether the instrument will maintain reliable performance in emergency situations, and whether the design change is implementable by all manufacturers. Additionally, the group developed a test evaluation for the discontinuous transmission mode.

Product Labeling

The Product Labeling Working Group assessed labeling possibilities in a number of areas, including exposure to radiofrequency energy, efficient phone operation, and electronic device compatibility. The group also evaluated a number of labeling methods and determined that a package insert would be the most appropriate way to disseminate the information.

Product Certification

The four categories of radiation standards include:

- Standards which specify safe exposure levels for humans
- Standards which limit the equipment's electromagnetic energy emissions
- Standards which are concerned with safe exposure levels for certain devices or materials (e.g., explosive devices or flammable materials)
- Interference standards limiting the impact of one emitting equipment on another electronic device

The certification effort involves the development of standardized testing techniques for evaluation of wireless instruments based on the Specific Absorption Rate

(SAR). Realistic worst-case exposures will be evaluated for comparison with established exposure guidelines.

During Phase One, the efforts of the Dosimetry Committee produced an overall certification strategy and work plan. The plan includes validation of the FD-TD method for application to exposure quantification from wireless instruments and reliable measurements of human exposure for comparison to existing exposure guidelines.

Several certification programs for wireless instruments are either currently in operation or are planned. The WTR has undertaken cooperative efforts with groups conducting such programs to assure consistency and comparability of generated data.

Usage Restrictions

The Usage Restrictions Working Group is charged with evaluating emerging scientific information and making usage recommendations that will serve to mitigate any identified public health risks. Members of this group are currently involved in fundamental research under the wireless technology program, addressing dosimetry and human exposure issues.

Infrastructure Modification — Base Stations

The Infrastructure Modification Working Group is charged with evaluating the types of infrastructure changes that might be feasible to modify power, and therefore radiofrequency radiation exposure, from wireless instruments and assessing any risks associated with proposed infrastructure modifications.

The primary determinant of the amount of power employed by a handset is the distance of the user from a base station. A wireless base station plays an essential role in the wireless network by acting as both a signal relay station and a telephone switching center. If possible mitigation of a public health threat from wireless instruments entails minimizing the power being emitted from the handset, then increasing the density of base stations in a community might be a way to manage risk. Recently, citizens in communities where base stations are to be sited have raised questions regarding potential adverse impact of these base stations.

During Phase One, the working group oversaw the development of preliminary data regarding basic usage patterns and infrastructure uses. General findings include the following:

Overall usage

- Call duration seems to be independent of system, geography, or demographics
- Around 80% of all calls are less than two minutes in duration, in both rural and urban areas

Patterns of users

- The majority of usage is in the lower-powered urban and suburban areas
- As the average usage increases, users tend to be located in the lower-powered environments

Overall system power trends

- As the systems grow, they tend to power down
- Powering down reduces the likelihood of portables operating at full power

Portable power trends

- The amount of time that a portable phone will operate at full power in an urban area could be as low as 5%; rural areas could have a minimum time of 50%

The working group sponsored a National Symposium on Wireless Transmission Base Station Facilities on October 28, 1994. Symposium participants included scientists, engineers, land-use experts, public policy officials, and economists from the Federal Government, academia, industry, and the non-profit community.

The symposium, coordinated by Federal Focus, provided an environment in which scientific information on base stations was shared and consolidated. Agenda sessions included a description of current and planned technologies, base station facilities and electromagnetic interference and compatibility, typical exposures to base station radiofrequency and exposure standards, and land use issues surrounding the siting of base stations.

A monograph is being prepared which compiles the information presented at the symposium and provides a primer on wireless technology and base station facilities.

Education and Scientific Outreach

This working group has been instrumental in the development and dissemination of information regarding the wireless technology research process, including both the risk evaluation and the risk management components. Some of the group's Phase One activities included: publication of the *Cellular Telephone Update* newsletter (now *Wireless Technology Update*), which has a circulation nearing one thousand; coordination of briefings regarding the wireless technology research program for the GAO, FDA, EPA, FCC, NTIA, OTA, HHS, Department of Commerce, U.S. Congress, and the White House; and coordination of informed responses to public, media, and scientific inquiries regarding wireless technology and the research program.

"The purpose of the symposium is to have experts share their insight and experience on the changing aspects of wireless transmission base station technology, and provide a forum for coordinating future scientific discussions."

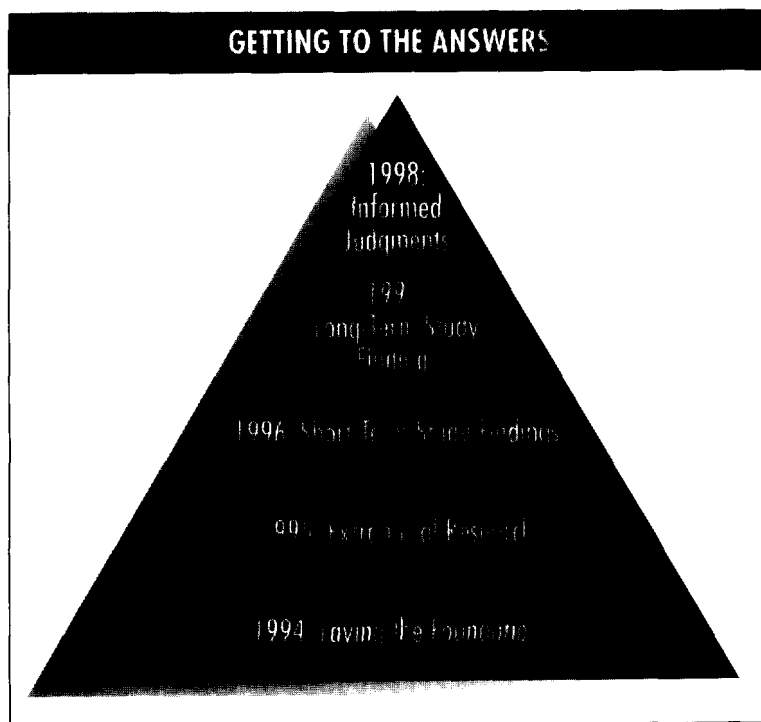
Dr. George L. Carlin
Base Station Symposium

October 1994

"The Scientific Advisory Group's program is one of the largest independent research efforts in the world. We are moving forward with the input of more than 150 scientists in the United States and abroad. In science, it is most important to be right, not hasty."

*Dr. George L. Carlo
Chairman*

December 1994



Report Recommendations

In November 1994, at the time the SAG forwarded the risk management status report to CTIA, the SAG made three specific recommendations to industry. These recommendations were not based on public health urgency, but as appropriate and effective steps to enhance and sharpen the industry's ability to be responsive should the need for risk management intervention arise. The recommendations were to:

- Adopt standardized labeling of wireless instruments
- Develop standardized information for dissemination to member companies and to the public

- Adopt an industry-wide instrument certification program that requires certified phones to meet all appropriate standards

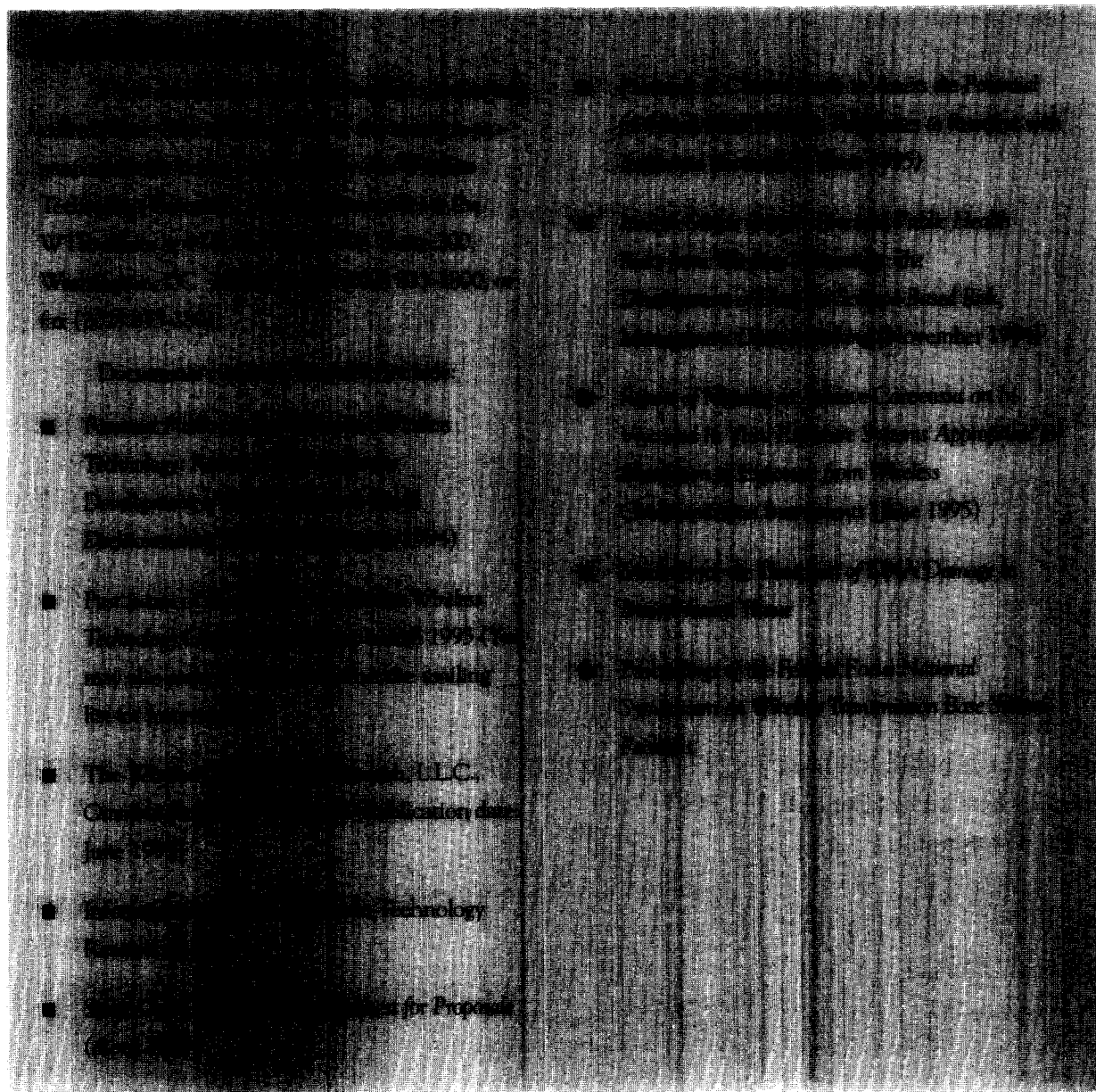
The SAG Product Labeling Working Group, in cooperation with the CTIA, developed guidelines for usage information to insert in new phone packaging. The SAG endorsed these efforts; however, as these guidelines do not address health concerns, the SAG recommended that CTIA explore the possibility of incorporating the FDA's talk paper, "Update on Cellular Phones" in the package insert to complement the usage guidelines.

The SAG also suggested that CTIA prepare and forward standardized material describing the scientific program and its progress to

its members. They recommended that the material be checked for accuracy by the SAG and organized to facilitate periodic updates. This material should form the basis for all information disseminated to the public.

Finally, the SAG recommended that the industry develop an independent structure through which those cellular telephone manufacturers who do not already do so have their products tested to ensure they meet current safety standards. The Product Certification Working Group is developing standardized guidelines to be used for certification.

APPENDICES



MEMBER BIOGRAPHIES



Dr. George L. Carlo is an epidemiologist and the chairman of Health & Environmental Sciences Group, Ltd., which specializes in assessing and managing risks to health, including risks from the environment, pharmaceuticals, and consumer products. He also studies the safety and efficacy of drugs and medical devices.

Dr. Carlo serves on the adjunct faculty of the George Washington University School of Medicine and Health Sciences. He previously served on the faculties of the University of Arkansas for Medical Sciences, the State University of New York at Buffalo School of Medicine, and the Roswell Park Memorial Institute.

Dr. Carlo served on the U.S. Congress Office of Technology Assessment Agent Orange Advisory Panel, currently chairs the Wireless Technology Research, L.L.C., is a member of the National Institute

for Allergy and Infectious Diseases' Low-Dose Oral Alpha-Interferon Clinical Trial Planning Committee, and is a scientific advisor to various private concerns. He is a Fellow of the American College of Epidemiology.

Dr. Carlo earned his B.A., M.S., and Ph.D. from the State University of New York at Buffalo. He earned his Juris Doctor from the George Washington University. He is a member of the Society for Clinical Trials, the Society for Epidemiologic Research, the American Public Health Association, and numerous other professional public health, science, risk analysis, and occupational and environmental health associations and organizations.

Dr. Carlo has published extensively, including research articles, commentaries, book chapters, and health policy papers addressing environmental, occupational, and public health issues and health sciences. He has been invited to testify before Congress, government, and regulatory agencies. Dr. Carlo has been listed in *Who's Who in Science and Engineering*, *Who's Who in Medicine and Healthcare*, and *Who's Who in the World*.



Dr. Arthur W. Guy is one of the world's leading experts on bioelectromagnetic research. A former President of the Bioelectromagnetics Society (1983-84), he has received numerous awards in the fields of bioelectromagnetics and microwave power. In 1993, he became a member of the SAG and, subsequently, the WTR.

During his early career, Dr. Guy served as Electronics Technician in the U.S. Air Force, Research Engineer in the Antenna Research Group, Boeing Aerospace Company, and Researcher on VLF antennas buried in polar ice caps for the Department of Electrical Engineering, University of Washington. He acted as Consultant to the Department of Rehabilitation Medicine, studying effects of electromagnetic fields (EMF) on living tissue, and joined the faculty in 1966.

At the University, Dr. Guy was Professor in the Center for Bioengineering, had a joint appointment as Professor in Rehabilitation Medicine and Adjunct Professor in Electrical Engineering, served as

Director of the Bioelectromagnetics Research Laboratory, and is presently Professor Emeritus in the Center for Bioengineering and Rehabilitation Medicine.

Dr. Guy is Vice Chairman of the Institute of Electrical and Electronics Engineers (IEEE) Standards Coordinating Committee SCC-28 on Nonionizing Radiation and a member of SCC-28 Subcommittee IV, which developed protection guidelines for human exposures to radiofrequency fields in 1974 and 1982. He is a member of the National Council on Radiation Protection and Measurement's Scientific Committee 89 on Nonionizing EMF and previously chaired its Scientific Committee 53, responsible for biological effects and exposure criteria for radiofrequency fields. He chaired the IEEE Committee on Man and Radiation (COMAR), is a member of the U.S. National Committee of the International Union of Radio Science (URSI) Commissions A and K, and has served on the U.S. Environmental Protection Agency Scientific Advisory Board Ad Hoc Committee on Biological Effects on Radiofrequency Fields. Dr. Guy was a participant in the US-USSR Environmental Health Cooperative Program from 1974 to 1983, and served on the editorial boards of several bioelectromagnetic journals prior to his retirement.

He received his B.S., M.S., and Ph.D. in Electrical Engineering from the University of Washington, Seattle. He holds memberships in Phi Beta Kappa, Tau Beta Pi, Sigma Xi, the American Association for the Advancement of Science and the American Polar Society, and is a Fellow of the IEEE and the International Microwave Power Institute.



Dr. Ian C. Munro is a leading authority on toxicology and has over 25 years experience in dealing with complex regulatory issues related to product safety. He has in excess of 150 scientific publications in the fields of toxicology and risk assessment. In 1993, he became a member of the SAG and, subsequently, the WTR.

Dr. Munro formerly held senior positions at Health and Welfare Canada as Director of the Bureau of Chemical Safety and Director General of the Food Directorate, Health Protection Branch. While with the Health Protection Branch, Dr. Munro was responsible for research and stan-

dard setting activities of the Branch related to microbial and chemical hazards in food and nutritional quality of the Canadian food supply.

He also has contributed significantly to the development of risk assessment procedures in the field of public health both nationally and internationally through membership in various committees dealing with the regulatory aspects of risk assessment and risk management of public health hazards. A member of the Board of Directors of the Toxicology Forum, Dr. Munro also holds memberships in the Society of Toxicology and the American College of Toxicology.

He has served on numerous national and international committees, including those of the World Health Organization, the International Agency for Research on Cancer, and the National Academy of Sciences. Dr. Munro is a fellow of the Royal College of Pathologists, London. He also was formerly Director of the Canadian Centre of Toxicology at Guelph, Ontario, and serves as adjunct professor in the Department of Nutritional Sciences at the University of Guelph.

Dr. Munro is a graduate of McGill University in Biochemistry and Nutrition. He also holds a Ph.D. from Queen's University in Pharmacology and Toxicology.

WIRELESS TECHNOLOGY RESEARCH, L.L.C.

10 April 1995

Keith O. Fultz
Assistant Comptroller General
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
441 G Street, N.W.
Washington, DC 20548

RE: **Telecommunications: Status of Research on the Safety of
Cellular Telephones, November 1994**

Dear Mr. Fultz:

After careful review of your evaluation of the status of research on cellular telephones, we are pleased to report that The Scientific Advisory Group on Wireless Technology (SAG) has adopted your recommendations regarding the independence and objectivity of our research program and the role of the federal government in the program.

As you are aware, our program was established in early 1993. The surveillance and research effort was launched pursuant to the wireless telecommunication industry's public commitment to support the funding of independent, rigorous scientific research into the public health impact of wireless technology. The independent scientific program we subsequently developed was framed in accordance with the following criteria:

1. The program must be independent of industry influence so that the results would be acceptable to public health decisionmakers in the scientific community, government, industry, and the community;
2. The program must adhere to the highest of scientific standards to guarantee scientific rigor;
3. The program must encompass a rapid trigger for public health intervention, if any adverse impact of wireless technology is discovered;
4. The program must encompass ongoing coordination with government decisionmaking bodies and the scientific community;
5. The program must involve significant funding to gain answers to critical public health questions in a defined time frame.

From the outset, the scientific rigor of our program has been built upon the expertise of the scientists and research institutions involved in this effort. In developing our research agenda, we reviewed all of the potentially relevant data available and drew upon the ideas of more than 150 of the most informed scientists around the world. We then subjected our research agenda to an exacting scientific peer review process by a Peer Review Board of esteemed public health professionals, coordinated through the Harvard University School of Public Health. As we proceed to the "extramural" stage of our work, in which we contract with expert scientific investigators at universities, laboratories and other facilities, we will continue to maintain ongoing interactions with scientists in government and private institutions, both in the United States and abroad. We will also require our contractors to submit their work for publication in the open scientific literature. We are confident that our program will provide comprehensive and essential information regarding any health risks from wireless technology.

From the beginning, we too have believed that the independence of our research effort was paramount to the usefulness of our work. To this end, we have relied upon the integrity of the scientists working in our program, the integrity of the prestigious institutions they represent, the integrity of the scientific peer review program, the openness of our processes, the involvement of the federal government, and the promise of industry to provide financial support without any effort to interfere with or influence the scientific work.

In your report, you implied that the promise of non-interference by industry was not sufficient to satisfy everyone that industry would not influence the scientific process. To address this issue constructively, we have adopted the GAO's recommendation of an independent, formal funding mechanism covering the entire research program.

As of March 31, 1995, a new administrative structure, Wireless Technology Research, L.L.C. (the WTR), will carry forward the implementation of the program as it enters its extramural stage. The WTR is an independent, non-profit organization that will be directed by the same persons who have been members of the SAG.

Adopting the GAO's recommendations, in the context of the extramural stage of the research program, necessitated expansion of the SAG's duties and responsibilities. The original structure of the SAG focused on developing the scientific underpinnings of the research program. The SAG entered into relatively small contracts and grants to provide for initial research. The extramural stage will involve large contracts and thus will require enhanced financial management capability. The WTR will furnish that capability, in addition to the scientific program management and analysis that the SAG provides. The WTR now has exclusive contracting authority, using unrestricted deposit-only funds in an escrow account financed by industry. It has also hired administrative staff to manage, audit and report on the flow of funds through the research program. The WTR's principles governing the management of the escrow account provide for full and public disclosure of the financial structure and will ensure the integrity of the program and the resulting research.

Finally, in keeping with your recommendation to enhance coordination with government agencies, I am pleased to report that, on March 17, 1995, we held the first in what will become regular working sessions with government agency scientists. This very productive day-long session was facilitated by Dr. Elizabeth Jacobson of the FDA, and included scientists from the FDA, EPA, FCC, NTIA, NCI and NIOSH.

We believe that incorporating the recommendations of the GAO has enhanced our program and we thank you for your thoughtful input.

Sincerely,



George L. Carlo, Ph.D., M.S., J.D.
Chairman

cc: The Honorable William J. Clinton
The Honorable Jack Fields
The Honorable Edward J. Markey
The Honorable Carlos J. Moorhead
The Honorable Thomas Bliley, Jr.
The Honorable John D. Dingell
The Honorable Henry A. Waxman
Chairman Reed Hundt
Commissioner James H. Quello
Commissioner Andrew Barrett
Commissioner Rachelle Chong
Commissioner Susan Ness
The Honorable David Kessler
The Honorable Phil Lee
The Honorable Carol M. Browner
Dr. Elizabeth Jacobson

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We wish to thank the following institutions for their contributions in helping lay the foundation for future research on wireless technology:

Academic and Scientific Research Institutions

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The Arthur G. James Cancer Hospital and Research Institute
AT&T Bell Laboratories
AUSA Research
Bailey Research Associates
Battelle Pacific
Northwest Laboratories
Ben-Gurion University of the Negev
The Bioelectromagnetics Society
British Columbia Cancer Research Centre
California Institute of Technology
Carnegie-Mellon University
The Catholic University of America
Centre International De Recherche Sur Le Cancer
Chemical Industry Institute of Toxicology
City of Hope National Medical Center
Clemson University
College of Physicians & Surgeons of Columbia University
Commsphere
COST 244
CSIRO Australia
Danish Cancer Society
Danish Institute for Clinical Epidemiology
ENSEIHT
Environmental Health Strategies, Inc.
Epidemiology Resources, Inc.
Electromagnetic Energy Association
European BioElectromagnetics Association
Finnish Centre for Radiation and Nuclear Safety (STUK)
Finnish Institute of Occupational Health
Ford Aerospace
Frederic Joliot-Curie
GenPharm International
Georgetown University
The George Washington University
Georgia Institute of Technology
Georgian Academy of Sciences
Harvard University School of Public Health
Howard University
IIT Research Institute
Inhalation Toxicology Research Institute
The Institute for Regulatory Policy

Institute of Experimental Radiology
Institute of Occupational Health
Integrated Laboratory Systems
International Epidemiology Institute, Ltd.
International Life Sciences Institute
International Union of Radio Science
Istituto Superiore di Sanita
IUSACELL, S.A. DE C.V.
Jewish General Hospital
John B. Pierce Laboratory
The Johns Hopkins University
Lenox Hill Hospital
Loma Linda University
Lund University Hospital
The Mayo Clinic
Medical College of Virginia
Medical University of Luebeck
Medical University of Montpellier/Nimes
Memorial Sloan-Kettering Cancer Center
Michigan State University
Mt. Sinai Hospital
New York Medical College
Northwestern University
Oak Ridge National Laboratories
Physiology Institute
Robert A. Taft Laboratories
Russian Academy of Sciences
Seattle City Light - EHS
Servizio Di Fisica Sanitaria
Sintef Unimed
Somerville College
Southwest Research Institute
State University of New York at Buffalo
State University of New York at Geneseo
Statistics Sweden (SCB)
The Swedish Council on Technology Assessment in Health Care (SBU)
Swiss Federal Institute of Technology
Technical University of Wroclaw
Telia Research AB
Thames Cancer Registry
TNO Defense Research
The Toxicology Forum
Trinity University
Underwriters Laboratories, Inc.
University of Alabama at Birmingham
University of Alberta
University of Bradford
University of California at Berkeley
University of California at Davis
University of California at San Francisco
University of Colorado at Boulder
University of Frankfurt
The University of Illinois at Chicago
University of Kansas
University of Kuopio
University of Maryland
University of Michigan
University of Minnesota
The University of North Carolina at Chapel Hill
University of Novi Sad
University of Oklahoma

University of Oxford
University of Pennsylvania
University of Rome "La Sapienza"
University of Surrey
The University of Texas Health Science Center at San Antonio
University of Turin
University of Utah
University of Victoria
University of Washington
University of Wisconsin Medical School
University of Zurich
Virginia Commonwealth University
VITO
Washington University
World Health Organization
Zoologisches Institute

Government Agencies, Departments, and Research Facilities

Armstrong National Laboratory
Brookhaven National Laboratory
Brooks Air Force Base
Department of Commerce
Department of Energy
Department of Health and Human Services
Department of the Air Force
Department of the Navy
Federal Communications Commission
Food and Drug Administration
National Cancer Institute
National Council on Radiation Protection and Measurement
National Institute of Applied Sciences
National Institute of Environmental Health Sciences
National Institute of Occupational Safety and Health
National Institute of Public Health
National Institutes of Health
National Radiological Protection Board
National Research Institute for Radiobiology and Radiohygiene
National Telecommunications Information Administration
Naval Aerospace Medical Research Laboratory
Occupational Safety and Health Administration
U.S. Congress Office of Technology Assessment
U.S. Environmental Protection Agency
U.S. General Accounting Office
U.S. House of Representatives
U.S. VA Medical Center
Veterans Administration Medical Center
Walter Reed Army Institute of Research
White House Office of Science and Technology Policy

Industry Support

AGT Mobility Inc.
ALLTEL Mobile Communications, Inc.
AMC Cellular Associates
AT&T
Activated Communications, Inc.
Advantage Cellular Systems, Inc.
AirTouch Cellular
Alpha Cellular dba Cellular One
American PCS, L.P.
American Portable Telecommunications
Ameritech Cellular Services
Appalachian Cellular Gen. Part.
Astronet
Atlantic Cellular Company
BC Tel Mobility Cellular Inc.
Bachtel Cellular Liquidity, L.P.
Baton Rouge Cellular Telephone Co.
Bell Atlantic Mobile Systems, Inc.
Bell Mobility
BellSouth Corporation
Blue Ridge Cellular, Inc.
Bluegrass Cellular, Inc.
Brazos Cellular Communications, Ltd.
Bristol Bay Cellular Partnership
C.C. Cellular
Cal-North Cellular
Carolina West Cellular
Cellular Communications, Inc.
Cellular Connection
Cellular Information Systems
Cellular Mobile Systems of St. Cloud
Cellular One - Kokomo
Cellular One - Sioux Falls
Cellular One of Amarillo
Cellular Plus
Cellular South
Cellular Telecommunications Industry Association
Cellular XL Associates, L.P.
Cellular of Upstate New York, Inc.
Century Cellunet, Inc.
Citizens Mohave Cellular
Clear Communications Group
Comcast Cellular Communications, Inc.
CommNet Cellular, Inc.
Cone Enterprises, Inc.
Copper Valley Cellular, Inc.
Cox Communications, Inc.
Dial Page, Inc.
Dobson Cellular Systems, Inc.
Durango Cellular Telephone Co.
ED TEL Mobility
Ericsson Radio Systems, Inc.
Farmers Cellular Telephone, Inc.
First Cellular of Southern Illinois
Forschungsgemeinschaft Funk
Frontier Corporation
Fujitsu Cellular
GTE Personal Communications Services
Geotek Communications, Inc.
HS Comm., Inc. dba New Wave Cell. Comm.
Highland Cellular Inc.
Horizon Cellular Group
Hughes Network Systems

Illinois Valley Cellular
Inland Cellular Telephone Co.
InterCel, Inc.
Kaplan Telephone Co. dba Pace Communs.
La Ward Cellular
Larsen Cellular Communications, Inc.
Leaco Rural Telephone Cooperative, Inc.
Liberty Cellular
Lincoln Telecommunications
Louise R. Hart
MACTel Cellular Systems
MINNESOTA RSA 9 LTD. PART.
MT&T Mobile Inc.
MTS Mobility
MUS CellularOne
Maine Cellular
Maine Wireless Limited Part.
McCaw Cellular Communications, Inc.
Mega Comm
Mercury Cellular & Paging
Mid-Missouri Cellular
Miscellco Communications, Inc.
Mitsubishi
Mo. RSA 5 Part./Chariton Valley Cell.
MobileTel, Inc.
Motorola, Inc.
NEC America, Inc.
Nebraska Cellular Telephone Corp.
New-Cell, Inc.
Nextel Communications, Inc.
Nokia Mobile Phones, Inc.
Northern Telecom Inc.
OKI Telecom
Oklahoma Western Telephone Co.
OneComm Corporation
Oneonta Telephone Co., Inc. dba OTELCO
Pacific Bell Mobile Services
Pacific Telecom Cellular
Palmer Wireless, Inc.
Panasonic
Peoples Cellular
Pine Cellular Phones
Pioneer/Enid Cellular
Point Communications Company
Poka Lambro Telecommunications, Inc.
PriCellular Corporation
Public Service Cellular, Inc.
Qualcomm Inc.
RAMCELL, INC.
RFB Cellular, Inc.
Rogers Cantel, Inc.
Rural Cellular Corp.
Rural Cellular Management
SLO Cellular, Inc.
SNET Mobility, Inc.
SYGNET Communications, Inc.
Santa Cruz Cellular Telephone, Inc.
Shenandoah Mobile Company
Sierra Cellular
Sony Corporation of America
South Alabama Cellular Communications
Southern Cellular, Inc.
Southwestern Bell Mobile Systems

Sprint Cellular
StarCellular
Sterling Cellular
NYNEX Mobile Communications
Telecommunications Industry Association
Texas RSA 1 L.P. dba XIT Cellular
Thumb Cellular Limited Part.
Toshiba America Consumer Products, Inc.
Triad Utah L.P.
TX RSA 15B2 L.P. dba Five Star Cellular
U S WEST NewVector Group, Inc.
Uniden America Corporation
Union Cellular
United States Cellular Corporation
Unity Cellular Systems, Inc.
Valley Telecom
Vanguard Cellular Systems, Inc.
Vitel Cellular
WESTERN MAINE CELLULAR, INC.
West Central Cellular
Western Wireless Corporation
Wireless One Network
WirelessCo

Many other unnamed individuals and institutions contributed to Phase One of our research program and to these we also extend our sincere thanks.

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ATTACHMENT B

POTENTIAL PUBLIC HEALTH RISKS FROM WIRELESS TECHNOLOGY:
RESEARCH AGENDA FOR THE DEVELOPMENT OF DATA
FOR SCIENCE-BASED DECISIONMAKING

Scientific Advisory Group

on

Cellular Telephone Research

August 25, 1994

be used as sources of information for more rigorous case-control epidemiological studies (Tierney and McDonald, 1991; Carson and Strom, 1986).

3.1.5 Clinical Studies

Clinical studies or clinical trials are tightly controlled, prospective evaluations of human subjects exposed to a particular drug, device or intervention. In most cases, clinical studies are designed specifically to investigate issues of safety and efficacy (Temple, 1981). In some cases, clinical studies are useful in defining exposure paradigms for epidemiological studies. As experiments, clinical studies are most definitive in the assessment of effects of exposures on humans (FDA, 1990). However, because human subjects are used, clinical studies are not commonly employed to test directly the safety of exposures such as those from wireless communications instruments.

3.1.6 Epidemiological Studies in General

Epidemiology is defined as the "study of the determinants of the frequency of disease" in human populations (Upton, 1990). Epidemiologists evaluate associations between disease and exposures, searching for cause-and-effect relationships. In general, epidemiological investigations compare either the occurrence of illness in exposed and unexposed groups (e.g., cohort studies), or the history of exposure in diseased and non-diseased groups (e.g., case-control studies) (Monson, 1990). The primary advantage of epidemiology studies is their direct relevance to humans and their ability to directly assess human health risk.

Because epidemiological studies are observational in nature, however, control for biases and confounding is critical to scientific rigor. In addition, precise exposure quantification is often difficult to achieve and in many instances epidemiological study results are equivocal or difficult to interpret. In those cases, information from toxicology and other scientific disciplines is useful to place the epidemiology results into scientific perspective.

In terms of determining carcinogenic potential, strong positive epidemiology is indicative of carcinogenesis, and only exposures where epidemiology studies have confirmed carcinogenicity can be classified as known human carcinogens (EPA, 1986; IARC, 1991). Conversely, the predictive value of negative epidemiology findings is

ATTACHMENT C

Assessment of Cellular Telephone and Other Radio Frequency Exposure for Epidemiologic Research

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Cellular Telephones and Health

The use of cellular telephones, first marketed in 1983, has increased exponentially during this past decade. A recent federal report¹ estimates that over 16 million Americans now use cellular telephones, and in 1994 the telecommunications industry estimated that over 60 million people will be using portable cellular communication devices by the year 2000. All devices that transmit radio frequency (RF) signals, such as radio broadcast towers and cellular telephones, emit radio frequency radiation. Cellular telephones are really mobile radios that operate at frequencies between 824 and 850 MHz (mobile units) and between 869 and 894 MHz (base stations). These frequencies are just above the UHF-TV portion and just below the microwave portion of the electromagnetic spectrum. Thus, although cellular is a new and rapidly growing communications medium, we have decades of experience with the underlying radio technology.

No research has been completed on long-term human exposure to low levels of radiation specifically from portable cellular telephones. Public concerns regarding the safety of cellular telephones heightened considerably in 1993 owing to publicity surrounding an anecdotal report in the news media. These concerns emphasized the need to assess the human health effects associated with use of cellular telephones. After this report was broadcast, a number of efforts were initiated by government and industry groups.

Epidemiologic research to date has found no persuasive evidence that low-power microwave radio communications signals adversely affect human disease. Similarly, the now fairly extensive research on the health effects of extremely-low-frequency (ELF) electric and magnetic fields has provided no conclusive evidence of an adverse effect on human health. It is estimated that population exposures resulting from base stations or cellular towers would be equivalent to that estimated from power transmission lines.

Current available research findings are insufficient to conclude that there are no long-term adverse health effects—either from handheld wireless communication devices or from cellular towers. This lack of evidence neither establishes the absence of an effect nor provides grounds for presuming that a hazard exists. It is this crucial gap that a large, new epidemiologic study of cellular telephone users seeks to address.

Two early reports in this issue,^{2,3} and an accompanying review of exposure assessment issues related to cellular telephones,⁴ represent the first phase of findings

from this research. The work is one component of a large, multifaceted research agenda funded by the telecommunications industry via a mechanism to ensure independence from industry influence.⁵ The epidemiologic component, reported for the first time here, is the establishment of a record-based mortality surveillance system for cellular telephone users. The challenges looming in this study are daunting, and the investigators are meeting the challenges head on. They have identified a way to enumerate an extremely large cohort of cellular telephone users and classified them in a way that provides a useful natural contrast: they compare mortality among users of portable cellular telephones, in which the transmitting antenna is in the handset, with that among users of mobile cellular telephones, in which the antenna is built into the automobile and not near the user's head. As a preliminary, they have surveyed a sample of cellular telephone users to identify characteristics that may influence exposure, and they have devised an unbiased way to estimate radio frequency exposure from billing records.

The report on the mortality experience of this cohort of cellular telephone users is a first look. It addresses only all-cause mortality for a short interval after exposure. Nevertheless, it provides a hint of what will be possible as the data accumulate over longer periods of time. Most importantly, these early results offer some reassurance, specifically that a large increase in mortality is not associated with radio frequency exposures over the short term.

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References

1. U.S. General Accounting Office. Telecommunications: Status of Research on the Safety of Cellular Telephones. Report to the Chairman, Subcommittee of Telecommunications and Finance, Committee on Energy and Commerce, House of Representatives. GAO/RCED-95-32. Washington DC: U.S. General Accounting Office, 1994.
2. Funch DP, Rothman KJ, Loughlin JE, Dreyer NA. Utility of telephone company records for epidemiologic studies of cellular telephones. *Epidemiology* 1996;7:299-302.
3. Rothman KJ, Loughlin JE, Funch DP, Dreyer NA. Overall mortality of cellular telephone customers. *Epidemiology* 1996;7:303-305.
4. Rothman KJ, Chou C-K, Morgan R, Balzano Q, Guy AW, Funch DP, Preston-Martin S, Mandel J, Steffens R, Carlo G. Assessment of cellular telephone and other radio frequency exposure for epidemiologic research. *Epidemiology* 1996;7:291-298.
5. Scientific Advisory Group on Cellular Telephone Research. Research response to public concerns regarding possible health effects from cellular telephones. Cellular Telephone Update 1993;1:1-2.